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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,545	07/14/2000	Toshio Ariyasu	Ariyasu=1A ✓	5549

1444 7590 04/14/2003

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/14/2003

#18

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED
18APR2003

AMD=14JL2003

RECEIVED
APR 18 2003
COMMERCIAL RELATIONS

Office Action Summary

Application No.

09/617,545

Applicant(s)

ARIYASU ET AL.

Examiner

Claire M. Kaufman

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003 and 06 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6, 7, 11-14 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6, 7, 11-14 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 4, 2003, has been entered.

Response to Amendment

The rejections of claims 5, 17 and 18 are moot in view of the cancellation of the claims.

The rejection of claims 2, 6, 7, and 11-14 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims and upon further reconsideration. Because the term "desert hedgehog protein of human origin" sufficiently defines the protein such that one skilled in the art would be able to readily recognize a protein isolated from a human as a desert hedgehog protein given the structural limitations of the amended claims, the teachings of the specification and, additionally, the teaching of desert hedgehog in the prior art (*e.g.*, Bitgood et al., Current Biol. 6(3):298-304, 1996).

The rejection of claims 11 and 14 under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims and upon further reconsideration for the reasons in the preceding paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 12, 20-23 and dependent claims 6, 7, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 20-22 are indefinite because it appears the DNA must encode a desert hedgehog protein and amino acid sequence SEQ ID NO:1 (or 2 or 3), but it is unclear if it is the hDhh (human desert hedgehog) protein that has SEQ ID NO:1 or if the DNA encodes 2 different sequences (the hDhh sequence and SEQ ID NO:1). Along the same lines, it is unclear if the complementary nucleotide sequence is that of the encoding hDhh sequence or SEQ ID NO:1. The "complementary" part of the claims makes it unclear because the DNA is being directly equated with a "nucleotide sequence", instead of the DNA having or consisting of a nucleotide sequence. If Applicants intend that the hDhh protein has the sequence of SEQ ID NO:1, the following claim language is suggested to overcome this rejection: An isolate DNA which encodes a dessert hedgehog protein of human origin having the amino acid sequence of SEQ ID NO:1, or an isolated DNA complementary thereto.

For the same reasons, claims 3-4 are also indefinite. It is unclear if the DNA encodes an hDhh protein and additionally contains SEQ ID NO:5 (or 6) or if the encoding sequence is that which contains SEQ ID NO:5 (or 6). As a result, it is unclear of what the complementary nucleotide sequence is.

Claims 2 and 23 are indefinite because if the DNA claims they depend on must encode, then the dependent claims cannot be complementary sequences. It is unclear if claims 2 and 23 are referring to the "complementary" sequence as the sequence complementary to SEQ ID NO:4 (or 5, respectively) or the "complementary nucleotide sequence" recited in the last lines of claims 20 and 23, respectively.

Claim 12 is indefinite for depending on cancelled claim 1.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1)a host which is a cultured cell or non-human animal,

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does not reasonably provide enablement for a host which is a transgenic human, and while being enabling for 2)a process of producing and collecting a desert hedgehog protein by expression a transformed DNA encoding a desert hedgehog protein of human origin which has been inserted into an autonomously replicable vector and introduced into a cultured cell, does not reasonably
5 provide enablement for a process of collecting said protein by expression in an animal, including a human, or plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification discusses *in vitro* expression and purification of a desert hedgehog
10 protein in cultured cells (paragraph bridging pages 8-9 of the specification), which were well known and routine techniques. Also described is the concept of *in vivo* expression in animals and plants (paragraph bridging pages 9-10), including in humans. The prior art teaches production of sonic hedgehog transgenic mice and zebrafish embryos (Echelard et al., Cell, 75: 1417-1430, and Krauss et al., Cell, 75:1431-1444, respectively). No collection of hedgehog
15 from transgenic animals is taught. The art of transgenics does not recognize as routine or well known the ability to make a transgenic human. Nor was it routine or well known at the time the invention was made to use transgenic animals to collect expressed proteins. This is especially true for hedgehog because of the processed hedgehog protein is secreted (*e.g.*, Echelard, *ibid.*, p. 1419, second full paragraph). Further, because of the lack of guidance or example of expressing
20 a hedgehog protein in plants, and because plants have cell walls distinct from animals, collection of an expressed mammalian protein such as hedgehog in a plant would require undue experimentation.

Conclusion

25 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5 Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

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Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

April 10, 2003